MANUFACTURER'S STATEMENT OF SUBSTANTIAL EQUIVALENCE

STATEMENT FOR INDICATIONS FOR USE:

The O'Neil Sterile Field Urinary Catheter Kit is suitable for the catheterisation of the bladder. It can be used for spinal patients, patients with urine retention, patients requiring intermittent bladder emptying, patients with strictures due to prostate problems and for checking residual urine after surgical procedures. The device will be available only by prescription and will carry the following legend: **"Caution : Federal Law restricts this device to sale by or on the order of a physician".** (21 CFR 801.109(b)(1))

CLAIMS REGARDING DEVICE FEATURES, PERFORMANCE, AND / OR SAFETY:

DESCRIPTION OF THE DEVICE:

The O'Neil Sterile Field Urinary Catheter Kit consists of a sterile catheter with introducer, Povidone Iodine swabsticks, gloves (latex or non-latex) and an underpad with waterproof backing. The kit has been designed to provide all the accessories required for ease of catheterisation of a patient.

When catheterisation of the patient is required, the underpad is laid under the patient, the gloves are used to protect the operator, the Povidone Iodine swabsticks are used to disinfect the area around the catheterisation site and the catheter with introducer is then inserted to catheterise the patient – see figures 1 & 2 for illustration of components in the kit. After successful catheterisation, all components are removed and discarded.

The catheter included in the kit is the "O'Neil Sterile Field Intermittent Urinary Catheter (K993651)", which is a device that has been successfully marketed in USA interstate commerce.

K002803
Page 2 of 2

The kit may be available with latex or non-latex gloves. For kits containing latex gloves, the warning, "This product is made from latex" will be included in the labelling – see Exhibit D for samples of labelling to be used.

The kit may also be available with triple Povidone Iodine swabsticks or single Povidone Iodine swabsticks.

VOLUNTARY AND MANDATORY STANDARDS:

Hennig Enterprises Europe srl is a fully compliant cGMP production facility which is registered by the FDA (facility number 9680787). Hennig Enterprises Europe srl is also authorised to use the CE Mark on its products, including the O'Neil Sterile Field Intermittent Urinary Catheter. The last inspection by the Notified Body was 23rd and 24th May 2000.

Go Medical Industries Pty Ltd is a fully compliant cGMP production facility which is registered by the FDA (facility number 9611004) and has been successfully qualified by FDA inspection – last inspection 16th-18th June 1999. **Go Medical Industries Pty Ltd** is also ISO 9001, EN 46001 certified and is authorised to use the CE mark on its products. The most recent CE surveillance audit was performed by the Notified Body on the 9th, 10th and 11th August 2000. Go Medical has also successfully qualified a Therapeutic Goods Administration (Australian Department of Health) audit for EN46001 certification on 4th November 1999.

PREDICATE DEVICE:

The subject device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials and mode of action are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2000

Dr. George O'Neil
Go Medical Industries Pty. Ltd.
200 Churchill Avenue
Subiaco Perth 6008
Western Australia
AUSTRALIA

Re: K002803
O'Neil Sterile Field Urinary Catheter Kit
Dated: December 05, 2000
Received: December 07, 2000
Regulatory Class: II
21 CFR §876.5130/Procode: 78 FCM, KOD

Dear Dr. O'Neil:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE STATEMENT

510 (k) Number: To be Assigned

Trade Name: **The O'Neil Sterile Field Urinary Catheter Kit**

Indications For Use:

The O'Neil Sterile Field Urinary Catheter Kit is suitable for the catheterisation of the bladder. It can be used for spinal patients, patients with urine retention, patients requiring intermittent bladder emptying, patients with strictures due to prostate problems and for checking residual urine after surgical procedures. The device will be available only by prescription and will carry the following legend: **"Caution : Federal Law restricts this device to sale by or on the order of a physician".** (21 CFR 801.109(b)(1))

David G. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002803

Prescription Use ✓
(Per 21 CFR 801.109)